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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

DAVIS, M

ART UNIT

PAPER NUMBER

1642

DATE MAILED:

05/24/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.
09/500,397

Applicant(s)

Soff et al

Examiner

Minh-Tam Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 15, 2001
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-75 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-75 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other:

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DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, 7-11, 14-16, drawn to a method of generating angiostatin *in vitro* comprising contacting plasminogen with a plasminogen activator and a sulhydryl donor, or contacting plasmin with a sulhydryl donor, classified in class 530, subclass 350.

II. Claims 5, 6, 12, 13, 17, 18, drawn to the method of group I, which further comprises administering to an animal the angiostatin produced *in vitro*, classified in class 514, subclass 2.

III. Claims 19-20, drawn to a method of treating an angiogenic disease comprising administering a sulhydryl donor, classified in class 424, subclass 9.1.

IV. Claims 19, 21, drawn to a method of treating an angiogenic disease comprising administering a sulhydryl donor and a plasmin, classified in class 514, subclass 2.

V. Claims 19, 22-24, drawn to a method of treating an angiogenic disease comprising administering a sulhydryl donor, a plasminogen activator, and a plasminogen, classified in class 514, subclass 2.

VI. Claims 25-27, drawn to a composition for generating angiostatin, comprising a sulhydryl donor, and a plasminogen activator, classified in class 530, subclass 350.

VII. Claim 28, drawn to a composition for generating angiostatin, comprising a conditioned culture medium, classified in class 424, subclass 520.

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VIII. Claim 29, drawn to a container holding a plasminogen activator and a label, classified in class 530, subclass 350.

IX. Claim 30, drawn to a container holding a plasminogen activator, and a sulhydryl donor and a label, classified in class 530, subclass 350.

X. Claim 31, drawn to a container holding a sulhydryl donor and a label, classified in class 530, subclass 2.

XI. Claims 32-34, 37, drawn to a method of generating angiostatin, comprising culturing cells, classified in class 424, subclass 93.7.

XII. Claims 35-36, drawn to the method of group XI, which further comprises administering to an animal the angiostatin produced *in vitro*, classified in class 514, subclass 2.

XIII. Claims 38-42, drawn to a protein that inhibits angiogenesis, classified in class 530, subclass 350.

XIV. Claims 43-46, drawn to a DNA molecule coding for a protein that inhibits angiogenesis, a host cell comprising said DNA molecule, and a method for producing a plasminogen fragment, classified in class 536, subclass 23.1.

XV. Claims 47, 49, 50, drawn to an antibody that binds selectively to native angiostatin, and a kit comprising a container holding the antibody, classified in class 530, subclass 387.1.

XVI. Claim 48, drawn to a method for detecting angiostatin, classified in class 435, subclass 7.1.

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XVII. Claim 51, drawn to a method for purifying a protein that inhibits angiogenesis, classified in class 435, subclass 7.1.

XVIII. Claims 52, 53, drawn to a method of treating an angiogenic disease comprising administering a protein that inhibits angiogenesis, or native angiostatin, or a kringle region fragment that has anti-angiogenic activity *in vitro*, classified in class 514, subclass 2.

XIX. Claims 54, 55, drawn to a method of treating an angiogenic disease comprising administering a transgene comprising DNA coding for a protein that inhibits angiogenesis, or native angiostatin, classified in class 514, subclass 44.

XX. Claims 56-58, drawn to a method of treating an angiogenic disease comprising administering a plasminogen activator, and a plasminogen, classified in class 514, subclass 2.

XXI. Claims 59-61, 65, 66, 69-72, drawn to a method of inhibiting angiogenesis comprising administering a kringle region fragment that has anti-angiogenic activity *in vivo*, and that comprises native angiostatin, or a fragment of native angiostatin, classified in class 514, subclass 2.

XXII. Claims 62-64, 67, 68, drawn to a method of inhibiting endothelial cell proliferation, comprising administering a kringle region fragment that has anti-angiogenic activity *in vitro*, and that comprises native angiostatin, or a fragment of native angiostatin, classified in class 514, subclass 2

In addition, upon the election of any of groups I, III, IV, V, VI, IX, X, further election of the following patentably distinct species of the claimed invention is required:

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Cysteine, N-acetyl cysteine, captopril, D-penicillamine, or reduced glutathione.

Upon the election of any of groups I, V, VI, VIII, IX and XX, further election of the following patentably distinct species of the claimed invention is required:

Urokinase, streptokinase, tissue plasminogen activator.

Upon the election of group XVIII, further election of the following patentably distinct species of the claimed invention is required:

A protein of claim 38, a native angiostatin, or a kringle region fragment.

2. The inventions are distinct, each from each other because of the following reasons:

Inventions (I-V, XI-XII, XVI-XXII) and (VI-X, XIII-XV) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05 (h)). In this instant case, a polypeptide could be used for several purposes, e.g. for biochemical assay, for making antibodies, and for making an affinity column to purify its antibodies; a DNA sequence could be used for the detection of similar DNA or RNA sequences, for making an expression vector, and for producing its encoded protein; and an antibody could be used for immunoassay, for purification of its antigen, and for detection of diseases.

The products of groups VI-X, XIII-XV are patentably distinct, because they are drawn to entirely different biochemicals or cell culture medium, having different structures, biological

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properties and activities. The product of group VI is distinct from the product of group IX, because the product of group IX contains the instruction label not found in group VI. Further, the structure of a sulhydryl donor, different proteins, antibodies and DNA are distinct.

The methods of groups I-V, XI-XII, XVI-XXII are distinct from each other because they differ at least in objectives, method steps, reagents and/or dosages, and/or schedules used, response variables and criteria for success. Further, inhibiting angiogenesis does not necessarily mean that endothelial cell proliferation is inhibited or a disease is treated.

The species cysteine, N-acetyl cysteine, captopril, D-penicillamine, or reduced glutathione are distinct because they are structurally distinct.

The species urokinase, streptokinase, tissue plasminogen activator are distinct because they are structurally distinct.

The species the protein of claim 38, a native angiostatin, or a kringle region fragment are distinct because they are structurally distinct.

Because these inventions are distinct for the reason given above and have acquired a separate status in the art as shown by their different classification, and because the searches for the groups are not co-extensive, restriction for examination purposes as indicated is proper.

Applicants are required under 35 USC 121 to elect a single disclosed group for prosecution on the merits to which the claims shall be restricted. Applicant is further advised that a response to this requirement must include an identification of the species that is elected

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consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 USC 103 of the other invention.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Minh-Tam B. Davis whose telephone number is (703) 305-2008. The

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examiner can normally be reached on Monday-Friday from 9:30am to 3:30pm, except on Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tony Caputa, can be reached on (703) 308-3995. The fax phone number for this Group is (703) 308-4227.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0916.

Minh-Tam B. Davis

May 15, 2001


SUSAN UNGAR, PH.D
PRIMARY EXAMINER